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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,533	06/30/2004	Gregory J Mazzola	P51318	4307

20462 7590 01/17/2007
SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/500,533

Applicant(s)

MAZZOLA ET AL.

Examiner

DiBrino Marianne

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-5, 7, 10-12, 14 is/are allowed.
- 6) ☒ Claim(s) 6,8,9,13,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/30/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 6/30/04 is acknowledged and has been entered.
2. The disclosure is objected to because of the following informalities:

The use of the trademarks SEPHAROSE and MACRO-PREP have been noted in this application, for example on page 5 at lines 35 and 37, page 13 at line 30, page 2 at line 32, page 8 at lines 29-30, page 6 at line 1. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction(s) is/are required.

3. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP § 608.01(b).
4. For the purpose of prior art rejections, the filing date of the instant claims is deemed to be the filing date of PCT/US03/00205, *i.e.*, 1/2/03, as the parent provisional application does not support the claimed limitations of the instant application, for example, it does not disclose the pH range recited in instant claim 1b "at about pH 5.0 to about pH 8.0", nor the limitation "in a solvent *comprising* dimethylacetamide".
5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 6, 8, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Claims 6 and 13 are indefinite in the recitation of "e. formulating the modified antibody-maytansinoid conjugate" because it is not clear what is meant and what the metes and bounds of the claim are.
 - b. Claims 8 and 15 contain the trademark/trade name SP-SEPHAROSE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or

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trade name. In the present case, the trademark/trade name is used to identify/describe an ion-exchange chromatography matrix comprised of sulfopropyl-SEPHAROSE and, accordingly, the identification/description is indefinite.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/00244 A2.

WO 01/00244 A2 teaches an antibody-DM1 conjugate wherein the antibody and DM1 Maytansinoid were linked using SSP (especially abstract, page 4 at lines 22-26, section "C." on page 37, Example 2).

The instant claims are included in this rejection because the recitation of the method by which the claimed antibody conjugate is produced carries no weight since the structure of the antibody conjugate is the same.

9. Claims 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/24763 A2 (IDS reference).

WO 01/24763 A2 teaches an antibody-DM1 conjugate wherein the antibody and DM1 maytansinoid were linked using SSP (especially abstract, Figure on the first page of document, pages 5, 6, 19, 20, 21, 32 and 35).

The instant claims are included in this rejection because the recitation of the method by which the claimed antibody conjugate is produced carries no weight since the structure of the antibody conjugate is the same.

10. Claims 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu *et al* (PNAS USA 1996, 93: 8618-8623, IDS reference).

Liu *et al* teach an antibody-DM1 conjugate wherein the antibody and DM1 maytansinoid were linked using SSP (especially materials and methods and abstract).

The instant claims are included in this rejection because the recitation of the method by which the claimed antibody conjugate is produced carries no weight since the structure of the antibody conjugate is the same.

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11. Claims 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu *et al* (Exp. Opin. Invest. Drugs, 1997, 6(2): 169-172, IDS reference).

Liu *et al* teach an antibody-DM1 conjugate wherein the antibody and DM1 maytansinoid were linked using a disulfide linker (see entire article).

The instant claims are included in this rejection because the recitation of the method by which the claimed antibody conjugate is produced carries no weight since the structure of the antibody conjugate is the same.

12. Claims 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith *et al* (Molec.Ther. 2001, 3(2): 198-203, IDS reference).

Smith *et al* teach an antibody-DM1 conjugate wherein the antibody and DM1 maytansinoid were linked using a disulfide linker (especially page 198).

The instant claims are included in this rejection because the recitation of the method by which the claimed antibody conjugate is produced carries no weight since the structure of the antibody conjugate is the same.

13. Claims 9 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Ross *et al* (Molec.Ther. 2001, 3(2): 198-203, IDS reference).

Ross *et al* teach an antibody-DM1 conjugate wherein the antibody and DM1 maytansinoid were linked using SSP (especially materials and methods and reference 11).

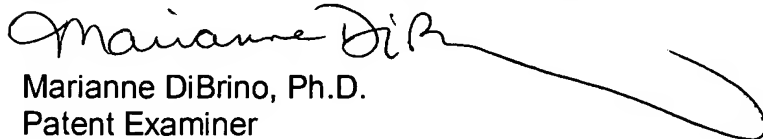
The instant claims are included in this rejection because the recitation of the method by which the claimed antibody conjugate is produced carries no weight since the structure of the antibody conjugate is the same.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
December 28, 2006



CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600